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Empowering Healthcare

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510(k) SUMMARY

McKesson Israel Ltd.'s Horizon Cardiology™

McKesson Israel Ltd.
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Israel
69710

Contact Person: Tomer Levy, VP Engineering
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Date Prepared: January 4, 2012

Name of the device:	Horizon Cardiology™
Common or Usual Name:	Imaging Processing System
Classification Name:	Picture archiving and communications system, 21 C.F.R. § 892.2050
Product code:	LLZ
Device Class:	II
Predicate Device:	Medcon Ltd. TCS(K974679) Philips's Xcelera (K061995) GE Medical Systems Information Technologies' Centricity (K063628)

Intended Use / Indications for Use

Horizon Cardiology™ is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital cardiovascular images.

Horizon Cardiology™ is intended for use in the Cardiology, Radiology or other departments throughout the healthcare facility and may be part of a larger PACS configuration.

Horizon Cardiology™ offers support for third party plug-ins in order to enable the use of commercially available tools for analysis, quantification and reporting.

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Technological Characteristics

Horizon Cardiology™ is an image processing system. The device consists of the following components and accessories: software application; database server; web server; application server; image and document storage server and media; long term archive and disaster recovery media; and client application workstation.

Performance Data

Verification and validation testing was performed on Horizon Cardiology™ to ensure it met all specifications. The device was further validated to ensure that it performs as intended. In all instances, Horizon Cardiology™ functioned as intended and the results observed demonstrate substantial equivalence with the predicate devices.

Substantial Equivalence

Horizon Cardiology™ is substantially equivalent to Medcon Ltd.'s TCS, as well as Philip's Xcelera, and GE Medical Systems Information Technologies' Centricity. Horizon Cardiology™ has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. All of the products are generally intended to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital medical images. In addition, the products have very similar indications for use.

The products also feature identical or very similar Client and Server operating systems, industry standards for system and network connectivity and communication (LAN, WAN, TCP/IP), image communication (DICOM), data exchange (HL7, PDF), file storage and management, and database engines. Moreover, all of the products feature structured templates for reporting on selected types of imaging. The minor technological differences between Horizon Cardiology™ and its predicate devices raise no new issues of safety or effectiveness. Thus, Horizon Cardiology™ is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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JAN 30 2012

Re: K112720
Trade/Device Name: Horizon Cardiology™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: LLZ
Dated: January 4, 2012
Received: January 4, 2012

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K112720

Indications for Use

510(k) Number (if known): K112720

Device Name: Horizon Cardiology™

Indications for Use:

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Prescription Use ____x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K112720